CLAIMS

What Is Claimed Is:

1. Apparatus capable of the non-contact or damage-free removal, break-down or erosion of undesirable deposits situated: (a) on or in an implanted artificial or bioprosthetic device having at least one moving or movable part or portion, or (b) on or in a natural bodily member or organ having a naturally moving part or portion, the deposits interfering or potentially interfering with at least one of (a) any designed function or maintenance of said implanted device, (b) any natural function of said natural bodily member or organ or (c) any circulatory system process necessary for normal healthy living, said apparatus comprising:

an acoustic emitter capable of emitting acoustic energy;

a means for exciting said acoustic emitter to emit acoustic energy;

a means for acoustically coupling said acoustic energy into said deposits directly or indirectly;

a means for operating said emitter(s) to at least partially remove, break-down or otherwise erode said deposits; and

optionally, an administered drug to aid said removal or erosion process, to prevent or slow further such deposits, or to treat a side-effect of treatment with said acoustic emitter.

2. The apparatus of Claim 1 wherein said at least one moving part is an occluder or leaflet in a natural, artificial or bioprosthetic valve anywhere in the body.

3. The apparatus of Claim 2 wherein said occluder, at least in part, is made of a biocompatible engineering material.

4. The apparatus of Claim 2 wherein said occluder, at least in part, is made of a tissue material of any type, natural or bioprosthetic.

5. The apparatus of Claim 4 wherein said tissue is, at least in part, donor human tissue, donor animal tissue, or lab-grown tissue.

6. The apparatus of Claim 2 wherein said occluder is a portion of a patient's own natural valve, anywhere in the body.

7. The apparatus of Claim 6 wherein said natural valve is a cardiac valve or a venous valve or a lymphatic valve.

8. The apparatus of Claim 1 wherein said deposits are on or in at least one of the moving or nonmoving parts of said implant, member or organ.

9. The apparatus of Claim 1 wherein at least some of said deposits interfere with the proper moving of a moving part of said implant, member or organ or interfere with a moving part or medical device arranged or designed to be passed through, passed into, mated to or threaded into said implant, member or organ.

10. The apparatus of Claim 1 wherein the presence of said deposits eases or encourages the formation of additional deposits.

11. The apparatus of Claim 1 wherein said deposits interfere with normal blood flow trajectories, normal hemodynamics or normal cardiac capacity.

12. The apparatus of Claim 1 wherein said emitter is acoustically coupled into said deposits directly using at least one of a noninvasive, minimally invasive or invasive approach.

13. The apparatus of Claim 1 wherein said non-contact deposition removal and lack of scratching or other damage to any portion of said implant, member or organ is provided by at least one of: (a) no portion of the emitter means contacts the implant, member or organ, (b) any portion of the emitter means that does contact the implant, member or organ is chosen to be a compliant or deformable material.

14. The apparatus of claim 1 wherein at least one implant, organ or member moving part or portion is at least temporarily immobilized by any placement of the emitter or any aspect of the therapy

15. The apparatus of Claim 14 wherein the immobilization is provided by the juxtaposition or insertion of a soft or compliant member that mechanically blocks said motion.

16. The apparatus of Claim 15 wherein the soft or compliant member is an inflatable balloon or other pressurized member.

17. The apparatus of Claim 16 wherein said inflation is by at least one of a liquid or a gas.

18. The apparatus of Claim 1 wherein said deposits at least in part, comprise one of (a) blood constituents, clotted or not, (b) calcium-containing materials, (c) fatty deposits, (d) bodily organic debris, (e) pannus, and (f) bacteria or bacterial infected matter.

19. The apparatus of Claim 18 wherein said deposits include endocarditis-causing bacteria or fungus, said deposits occurring in, around or in infectious association with a natural or prosthetic valve or implant.

20. The apparatus of Claim 19 wherein said acoustic emissions result in at least one of (a) directly destroying said deposits, (b) thermally destroying said deposits, (c) plugging a blood-leak caused by such deposits, (d) plugging a blood-leak and simultaneously killing at least some of said deposits, and (e) serving as a therapy for endocarditis.

21. The apparatus of Claim 20 wherein acoustic emissions are directed at at least some said deposits surrounding a natural or prosthetic valve and said deposits are at least partly killed by at least one of direct acoustic radiation or heat generated by acoustic radiation.

22. The apparatus of Claim 20 wherein acoustic emissions are directed, at least in part, to a prosthetic valve component whereby acoustic heating of said component causes heat to be conducted into adjacent endocarditis-laden tissue, said endocarditis bacteria or fungus being at least in part killed by said conducted thermal energy.

23. The apparatus of Claim 20 wherein a drug acting against endocarditis is locally or systemically delivered to said valve or implant in any manner.

24. The apparatus of Claim 23 wherein said localized delivery is by delivery of the drug from an inflatable balloon.

25. The apparatus of Claim 20 wherein said acoustic emissions are delivered to the valve or implant from a catheter or other lumen-delivered device.

26. The apparatus of Claim 1 wherein said drug is employed at least one of before, during or after an acoustic exposure in order to aid in removal, breakdown or erosion of said deposits or to ameliorate a side-effect of the acoustic therapy.

27. The apparatus of Claim 26 wherein said acoustic energy accelerates or enables any favorable action of said drug.

28. The apparatus of Claim 1 wherein said acoustic energy has a frequency with a wavelength on the order of a characteristic dimension of said deposits or of a deposit constituent in order to enhance acoustic coupling to the deposit or deposit constituent.

29. The apparatus of Claim 1 wherein said acoustic energy has a frequency with a wavelength which purposely excites a resonance or resonance harmonic in a portion of the implanted device or purposely avoids such a resonance.

30. The apparatus of Claim 29 wherein said resonant excitation contributes to indirect delivery of acoustic energy into said deposits and said indirectly-delivered energy contributes to removal, break-down or erosion of said deposits.

31. The apparatus of Claim 1 wherein said acoustic energy causes at least one of blood streaming, cavitation, erosion, break-down or dissolution in the region of said deposits.

32. The apparatus of Claim 31 wherein said streaming or cavitation aids the removal, break-down or erosion of at least a portion of said deposits.

33. The apparatus of Claim 1 wherein said acoustic energy aids in the permeation of said deposits by at least one of a drug or a blood constituent.

34. The apparatus of Claim 1 wherein the removal of said deposits prevents a potential stroke or any cardiac dysfunction or degraded function.

35. The apparatus of Claim 1 wherein said drug is selected from the group consisting of (1) thrombolytic therapy or clot-dissolving drugs, (2) tissue plasminogen activators or a type thereof, (3) anti-clotting, anti-coagulant or anti-platelet drugs, and (4) thrombin inhibitor or anti-platelet drugs.

36. The apparatus of Claim 35 wherein said drug is selected from the group consisting of alteplase, anistreplase, streptokinase, urokinase, warfarin, heparin, lepirudin, aspirin, ticlopidine, clopidogrel, tirofiban, and eptifibatide.

37. The apparatus of Claim 35 wherein said drug is utilized at least one of before, during or after said treatment.

38. The apparatus of Claim 1 wherein two or more therapy sessions are conducted at different times or on different days.

39. The apparatus of Claim 1 wherein said implant includes a valve or occluder of any type supportive of a patient's cardiac, lymphatic or arterial systems.

40. The apparatus of Claim 39 wherein said implant includes at least one biocompatible engineering material in its construction.

41. The apparatus of Claim 39 wherein said implant includes at least one artificial or donor-tissue material in its construction.

42. The apparatus of Claim 1 wherein a balloon or other soft standoff or appendage is interspersed between said emitter and any portion of said implant, member or organ and passes emissions to or from said implant, member or organ in a manner avoiding damage or scratching of said implant, member or organ.

43. The apparatus of Claim 1 wherein a balloon, standoff or appendage is utilized to aid in the temporary clamping or holding of said moving part of said implant, member or organ such that at least one deposit can be better accessed, inspected or treated.

44. The apparatus of Claim 43 wherein said moving part of said implant, member or organ is an occluder.

45. The apparatus of Claim 1 wherein said direct energy deposition upon or into said deposits involves said emissions passing through at least one blood, liquid or tissue path between said emitter and said deposits.

46. The apparatus of Claim 1 wherein said indirect energy deposition upon or into said deposits involves said acoustic emissions first coupling into said implant, member or organ and then said acoustic energy in turn being delivered to a deposit from the implant, member or organ it is resident upon or within.

47. The apparatus of Claim 1 wherein said acoustic energy at least one of (a) does not appreciably resonate said implant, member or organ at one of its resonant frequencies that could otherwise cause damage thereto or (b) does appreciably resonate said implant, member or organ at an implant resonant fre-

quency but does so at an amplitude level below that known to damage said implant, member or organ.

48. The apparatus of Claim 1 wherein said deposits' interference with the designed or natural function of said implant, member or organ comprises interference in the desired hydrodynamic operation of a natural or implanted valve supporting the heart, the lymphatic system or the arterial system.

49. The apparatus of Claim 48 wherein said deposits are on a seat or sealing edge or face of said valve, in a hinge, pivot or flexural area of said valve, or on an occluder component or leaflet of said valve.

50. The apparatus of Claim 1 wherein said deposits include pannus growth and said acoustic energy is used to either stop said pannus growth or remove said pannus growth by cavitation, heating or thermal necrosis.

51. The apparatus of Claim 1 wherein said acoustic emitter is at least temporarily integrated either into the patient's body or into said implant itself.

52. The apparatus of Claim 51 wherein said acoustic emitter can be automatically operated without constant patient or doctor manipulation.

53. The apparatus of Claim 1 wherein said acoustic emitter is one of a piezoelectric, ferroelectric, electrostrictive, magnetostrictive, optoacoustic or thermoacoustic emitter.

54. The apparatus of Claim 1 wherein said acoustic emitter is integrated or co-mounted with an imaging device selected from the group consisting of an ultrasound transducer, an infrared camera or an imaging scope of any type.

55. The apparatus of Claim 1 wherein an independent imaging device is employed to guide or plan said treatment.

56. The apparatus of Claim 55 wherein the independent imaging device is one of (a) ultrasound imaging, (b) fluoroscopy, (c) MRI, (d) CAT scan, (e) PET, or (f) videoscope with a waterpath.

57. The apparatus of Claim 1 wherein said drug is locally delivered to said deposits in any manner.

58. The apparatus of Claim 57 wherein said local delivery is via a catheter or working port of a scope.

59. The apparatus of Claim 1 wherein said acoustic energy is coupled into said implant, member or organ by (a) coupling to a patient's external skin, (b) coupling from within a patient's natural body passage or space, (c) coupling into the surface of a surgically exposed or accessed organ or tissue surface, (d) coupling from a lumen as by a catheter, or (e) coupling from within a cardiac chamber or flowpath.

60. The apparatus of Claim 1 wherein said acoustic emitter also comprises or is co-mounted, co-packaged or used in association with an acoustic device used to gather an acoustic fingerprint indicative of the extent, location or nature of deposits.

61. The apparatus of Claim 1 wherein one or more acoustic fingerprints are taken or generated by an at least second acoustic device independent of said acoustic emitter, the acoustic fingerprint or fingerprints being indicative of the extent, location or nature of deposits.

62. The apparatus of Claim 1 wherein a suction device, catching filter or other trapping means is used to collect or at least immobilize debris removed from said implant during said treatment or by said treatment.

63. The apparatus of Claim 1 wherein debris generated by said treatment is arranged to be of sufficiently fine size that it can be allowed to pass into the circulatory system safely.

64. The apparatus of Claim 1 wherein said deposits comprise at least one of (a) surface-deposited, calcium-containing material, (b) calcium-based deposits inside tissues or in tissue interfaces, (c) calcium-based deposits inside implant materials or in an interface including at least one implant material, (d) fatty deposits on surfaces or inside tissues or engineering materials, (e) organic debris on surfaces or inside tissues or engineering materials, (f) plaque-like deposits, and (g) any deposit which contributes to stenosis or a loss of elasticity of a moving or movable tissue or implant component.

65. The apparatus of Claim 1 wherein said acoustic energy is within a range of 1 Hz to 100 MHz.

66. The apparatus of Claim 65 wherein said acoustic energy is within a range of 1 KHz to 10 MHz.

67. The apparatus of Claim 66 wherein said acoustic energy is within a range of 5 KHz to 10 MHz.

68. The apparatus of Claim 65 wherein said acoustic energy is chosen to either: (a) not excite a known resonance of said implant, or (b) to excite a known resonance of said implant below an amplitude that would damage the implant.

69. The apparatus of Claim 65 wherein any parameter of said acoustic energy is chosen for its ability to remove said deposits upon direct radiation by said acoustic energy.

70. The apparatus of Claim 1 wherein said acoustic energy has an acoustic power within a range of milliwatts/cm^2 to kilowatts/cm^2.

71. The apparatus of Claim 70 wherein said power is within a range of 0.5 to 5,000 watts/cm^2.

72. The apparatus of Claim 71 wherein said power is within a range of 5 to 500 watts/cm^2.

73. The apparatus of Claim 1 wherein said acoustic energy is delivered by at least one of a focused, unfocused or collimated beam transducer and said acoustic emitter is at least one of mechanically focused or electronically focused.

74. The apparatus of Claim 1 wherein said deposits comprise pannus.

75. The apparatus of Claim 74 wherein said acoustic energy has a frequency within a range of 3 to10 MHz and an acoustic power of several hundred to a few thousand watts/cm^2 at the most intense portion of the beam.

76. The apparatus of Claim 74 wherein said acoustic energy causes said pannus to be killed via thermal heating and/or cavitation.

77. The apparatus of Claim 1 wherein said acoustic energy causes beneficial cavitation, said cavitation optionally being aided by the presence of cavitation nuclei or facilitators.

78. The apparatus of Claim 77 wherein said cavitation nuclei or facilitators are selected from the group consisting of contrast microbubbles, gas bubbles, and surfactants.

79. The apparatus of claim 1 wherein the deposits are present in or on a body organ undergoing perfusive motion, the perfusive motion being interfered with directly or indirectly, at least locally, by the deposits.

80. The apparatus of claim 79 wherein the member is any one of a heart, kidney, liver, muscle or tendon.

81. The apparatus of claim 1 wherein the deposits are present in, on or near an implant and they potentially interfere with maintenance, repair or removal of any portion of the implant.

82. The apparatus of claim 81 wherein the movable member comprises the desired moving of an implant portion to be maintained, serviced, replaced or removed.

83. The apparatus of claim 1 wherein the emitter therapy allows for a reduction in the use of any anti-deposit drug or avoidance of use of any anti-deposit drug which would have been otherwise used, at any point, if not for the availability of the emitter therapy.

84. The apparatus of claim 1 wherein the member is a temporary implant such as a drain or port, the drain or port requiring unimpeded passage through it and being subject to blockage, fouling or plugging by a deposited material which desires to be avoided.

85. An acoustic method capable of the non-contact removal, break-down or erosion of undesirable deposits on or in an implant comprising an implanted artificial or bioprosthetic device having at least one moving or movable part or portion, the deposits interfering or potentially interfering with at least one of (a) the designed proper functioning or maintenance of said implant or (b) a natural circulatory system process necessary for normal living, said method comprising:

providing an acoustic emitter capable of emitting acoustic energy;

exciting said acoustic emitter to emit said acoustic energy;

acoustically coupling said acoustic energy into said deposits, directly or indirectly, to at least partially remove, break-down or otherwise erode said deposits;

either passing said at least partially removed deposits or otherwise broken-down or eroded deposits into the body or physically removing said at least partially removed deposits or otherwise eroded or broken-down deposits by a collection or trapping means; and

optionally administering a drug to aid said removal,

said deposits thereby being at least partially removed from said implant.

86. A method of assessing the state of fouling by undesirable deposits of an implant or of a natural valve in a living body, the implant or valve having at least one moving or movable part, said method comprising:

obtaining, in any manner, an acoustic signature of the operation of said implant or valve or valve-model at least under unfouled conditions inside or outside a living body;

obtaining, in any manner, using passive reception or pulse-echo active probing, an acoustic signature of said implant or valve thought to possibly have fouling thereon or therein;

the possibly-fouled signature containing at least one of: (1) naturally generated acoustic features known to be caused by fouling, and (2) artificially excited features known to be excited upon the presence of fouling;

comparing the fingerprints looking for fouling features that have newly been incorporated into the signature; and

concluding that newly added features which match known fouling features indicate fouling.

87. The method of Claim 86 wherein said acoustic signature fouling feature relates to acoustics generated by a fouling deposit or modifications to the normal unfouled acoustics expected of an unfouled moving or movable implant part or of blood moving therein or thereby.

88. The method of Claim 86 wherein said implant or valve is imaged and said acoustic signature is synchronized with the motion of said implant or valve.